

Donald F. Fernholz

Senior Consultant/Auditor

EAS Consulting Group, LLC

1940 Duke Street, Suite 200

Alexandria, Va. 22314

Education: **Northern State University, Aberdeen, South Dakota**
BS Degree - Majors: Biology and Social Science

Professional Experience: **Minnesota State Health Department (one year)**
St. Paul, Minnesota

Position: State Health Sanitarian. Made sanitary inspections of food establishments, restaurants, resorts.

U. S. Food and Drug Administration

Position: Consumer Safety Officer

St. Louis, Missouri (one year)
Minneapolis, Minnesota (one year)
Chicago, Illinois (seven years)
Fargo, North Dakota (four years)

Position: Supervisory Consumer Safety Officer

Akron, Ohio (ten years)
Brunswick, Ohio (ten years)

As a Consumer Safety Officer, made inspections of all types of food, drug, cosmetic, veterinary drug, device, blood bank, plasmapheresis, and medicated feed manufacturers.

Food manufacturing facilities were inspected for compliance with Good Manufacturing Practices regulations; HACCP regulations, if applicable; Low Acid Canned Food regulations; and other regulations.

Have made numerous inspections of on-farm custom feed mixing operators; medicated feed manufacturers; and have made numerous on-farm inspections to investigate drug tissue residue referrals from the USDA.

Have made numerous investigations of incidents involving food poisonings, adverse drug reactions, food and drug contamination incident

As a Supervisory Consumer Safety Officer, I hired and trained numerous investigators in all aspects of inspections, investigations, and evidence development.

I have received numerous awards during my career with FDA including:

Commendable Service Award, "For sustained superior performance in the timely processing of heavy workloads and high priority work with outstanding results"

Commendable Service Award, "For exemplary performance in managing the operations of District inspection posts".

Letter of Commendation from President Regan for the investigation of a drug tragedy.

Seminars/Courses:

I presented training in several courses in "Evidence Development" to investigators throughout FDA Region V and received a Letter of Commendation for my efforts.

I was a facilitator for a series of "Investment In Excellence" training courses and taught these courses in two FDA regions. I received a Letter of Commendation.

I have been a guest lecturer to students for the North Dakota State University, Akron University, and numerous lay groups. Presentations covered FDA law, recall policy, product labeling, evidence development, and several other topics related to FDA.

Additional Professional Activities

I have presented numerous training courses to FDA personnel, State and Local Health Department officials and others. The course content included inspection/audit techniques, Good Manufacturing Practices

regulation evidence development, documentation, HACCP regulations, Low Acid Canned Food regulations, and many other topics.

Position: Senior Auditor/Consultant

I have worked as a Senior Auditor/Consultant for two firms and as a self-employed Auditor/Consultant for the past ten years. This included audits and investigations of manufacturers, distributors, warehouses, and growers of a multitude of food products; dietary supplements, misbranded drugs, and food poisoning incidents.

Professional Memberships

Past member of: Central States Association of Food & Drug Officials
National Environmental Health Association
American Institute of Baking

Training Courses Attended

I have attended numerous training courses to include:

"Quality Audits for Improved Performance"
"FDA Law & Evidence Development"
"Advanced Course for Drugs and Parenterals"
"Low Acid Canned Food Processing"
"Advanced Course Non-Clinical Bio-Research"
"Milk Pasteurization Controls and Tests"
"Current Concepts in Food Protection"
"Medical Pharmacology Course"
"Statistical Quality Control"
"Advanced Course for Drug Inspectors: Blood Banks"
"Hazard Analysis and Critical Control Points"
"Good Agricultural Practices" audits


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